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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/661,965      | 09/12/2003  | David Christianson   | E0615-00060         | 8986             |

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EXAMINER

VOLLANO, JEAN F

ART UNIT PAPER NUMBER

1621

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/661,965 | <b>Applicant(s)</b><br>CHRISTIANSON ET AL. |  |
|                              | <b>Examiner</b><br>Jean F. Vollano   | <b>Art Unit</b><br>1621                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Priority*

1. The first sentence of the specification has the following: "This application is a continuation of U.S. patent application 10/053,939 (pending), which is a divisional of U.S. patent application 09/545,737 (now U.S. Patent No. 6,387,890), which is itself a continuation-in-part of International Patent Application PCT/US98/21430, published in the English language on October 9, 1998, and is entitled to priority pursuant to 35 U.S.C. 119(e) to U.S. provisional patent application 60/061,607, filed October 10, 1997."

The current status of all nonprovisional parent applications referenced should be included in the first sentence of the specification. Application 10/053,939 is no longer pending and the US patent no 6,723,710 should replace (pending). Please make appropriate corrections.

### *Claim Rejections - 35 USC § 112*

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the limitation of a compound wherein the NH<sub>2</sub> appears to be behind the plane and it is being assumed that the compound being claimed is a stereoisomer. However there is no such formula given in the specification and although there are some specific stereoisomers

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given which applicant has support. The examiner can find no support in the specification for the generic claim of any compound as a specific stereoisomer. Applicant is asked to limit the claims to the specific isomers for the specific compounds given in the specification or to show support for the claimed isomers in claim 1, 2, and 4.

Claim 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of a structure wherein there is a bond on the NH<sub>2</sub> which appears to be behind the plane. The other moieties on the carbon are a hydrogen a carboxylate and a X<sub>1</sub>X<sub>2</sub>... B(OH)<sub>2</sub>. It is confusing why the NH<sub>2</sub> is away from the plane and nothing else is forward to show which groups are together. The usual convention is the lowest group (in this case hydrogen) pointed back and then the R or S is determined by the clock wise or counterclock wise rotation of the remaining groups in order of priority based on the R or S rules. The examiner is not sure what exactly is the stereochemistry that is trying to claim. It might be more helpful to claim R or S if there is support in the specification for the designations.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 4 rejected under the judicially created doctrine of double patenting over claim 1-2 of U. S. Patent No. 6,723,710 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The composition being claimed in the instant invention is one stereoisomers that make up the composition and pharmaceutical composition with a carrier of claims 1 and 1 of US 6,723,710. In the US patent the claim is to the racemic form of the structure and the scope of the claim 1 is slightly narrower since the in the US patent X1, X2, X3 and X4 cannot at the same time be CH2. However the instant application does not remove that species from instant claim 1 or instant claim 4 otherwise the claims are the same except for the specific chiral center being claimed. Since the chiral centered component is in the racemic structure claimed in US 6,723,710 they are obvious variants.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Baggio et al ( J. Am. Chem. Soc. 119 Aug 1997).

Baggio et al discloses 6-borono L-norleucine as a hydrochloride salt in a pharmaceutical composition then the claims are fully anticipated.

The structure drawn in the claims could be an L or a D however it is unclear and as such all the rejections concerning the structure will be given.

3. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (US4477391).

Collins et al teaches a compound of formula 1 wherein one terminal end of the molecule is boronic acid and the linker is a 3-6 alkyl chain and the other terminal end is a CH group with an amine and a carboxylic acid functionality ( see column 1, and abstract).

Collins teaches that the compounds are D isomers(see abstract).

Collins teaches that the compounds are useful as pharmaceuticals (see column 1 and column 5, lines 6-14).

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Although the specific  $(\text{CH}_2)_4$  linker is not specifically disclosed it is expressly suggest in a small group of alkyl linkers (i.e. preferably C3-C6)( column 1, lines 46-47 and column 3 line 65) and it would have been obvious to one of ordinary skill in the art to have prepared the composition as a pharmaceutical for administration by the various routes of Collins ( see column 5, lines 10-20) with the expectation of having additional pharmaceutical compositions which would be useful in vivo as taught by Collins.

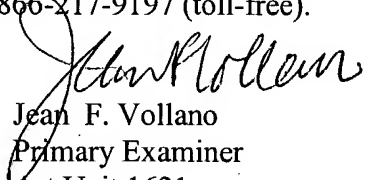
It is also noted that the optically active base used in the purification is lysine which has a  $\text{OHC}=\text{O CHNH}_2 (\text{CH}_2)_4$  core and would fit exactly with the  $\text{OHC}=\text{OCHNH}_2 (\text{CH}_2)_4$  boronic acid to produce the DL acid base complex . Also the claims suggest a pentyl R group which is a homologue of the group being claimed and thus there is a teaching towards the alkyl with about 4 carbons in a linear alkyl chain (see claims7-11) .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean F. Vollano whose telephone number is 571-2720648. The examiner can normally be reached on Monday-Thursday 6:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272- 0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean F. Vollano  
Primary Examiner  
Art Unit 1621

April 26, 2004